

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO Box 1430 Alexandria, Virginia 22313-1450 www.tepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,015	01/30/2006	Kazuyoshi Yano	3462.1014-000	1671
21005 7590 1223125099 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER	
			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1795	•
			MAIL DATE	DELIVERY MODE
			12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/533.015 YANO ET AL. Office Action Summary Examiner Art Unit KAJ K. OLSEN 1795 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 22 September 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-10 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 22 September 2009 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/G5/08)
 Paper No(s)/Mail Date ______.

Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Art Unit: 1795

DETAILED ACTION

Drawings

The examiner acknowledges the corrected drawings filed on 9/22/2009. The objection to
figures 1 and 3 is withdrawn in view of the corrected drawings. However, the figure 2 submitted
appears to be even worse than the previous figure 2 and is still unreadable. Hence, fig. 2 is still
objected to.

Specification

 The previous objection to the specification is being withdrawn in view of the 9/22/2009 amendment.

Claim Rejections - 35 USC § 112

 The outstanding 112 rejections have been withdrawn in view of the amendment to the claims

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (USP 4,676,274). Brown is being cited and relied on for the first time with this office action.

Art Unit: 1795

6. With respect to claim 1, Brown discloses a method of controlling the transfer of one or more liquid substances from a first cavity to the second cavity (e.g. 102 and 106 respectively of fig. 12) comprising introducing a fluid into a first cavity 102 whose transfer is to be controlled and holding said liquid in the first cavity which is connected to a second cavity 106 via an intermediated cavity 104 that is filled with a gas material that prevents transfer of liquid into the intermediate cavity. See col. 8, 1. 11 - col. 9, 1. 21. Brown further discloses that when the intermediate cavity is then vented, the gaseous separation medium is replaced with a liquid medium in the intermediate cavity (i.e. a connecting medium). The presence of this connecting medium thereby then allows fluid transfer from the first cavity to the second cavity owing to the removal of the liquid-air junction (col. 8, 11. 22-32).

- With respect to claim 2, the embodiment of fig. 8 utilized the device for separating cells from a fluid using mechanical pumping (col. 12, Il. 23-60).
- 8. With respect to claim 6, see the discussion above concerning the presence of a first cavity 102, a second cavity 106, and an intermediate cavity 104 where the intermediate cavity can hold a separation medium (gas) to hold fluid in the first cavity or a connection medium (fluid being transferred) which allows fluid to be transferred from the first cavity to the second cavity. With respect to the various limitations starting with "wherein the separation medium is replaced", these remaining limitations only further define the intended use of the device and do not further define the actual structure. The intended use need not be given further due consideration in determining patentability. However, see the discussion of claim 1 above how Brown anticipates the set forth use of the intermediate cavity.
- With respect to claim 7, see the discussion of claim 2 above.

Art Unit: 1795

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 2002/0170825) in view of Brown and with or without either Sundberg et al (USP 6,090,251) or Hochstrasser (USP 4,874,490). Sundberg is being cited and relied on for the first time with this office action.
- 13. With respect to claim 1, as discussed in the previous 6/1/2009 office action, Lee discloses all the limitations of the first cavity 3, second cavity 4, but does not explicitly teach the presence of intermediate cavity that connects the first and second cavities, but does discuss that it would be desirable to control the filling of each of the cavities (i.e. microchannels) separately (e.g. par. 0043 and 0044). The previously discussed Brown teaches the use of intermediate cavities

between two different cavities (i.e. capillary channels) for controlling the fluid flow from one cavity to the other. See the rejection above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an intermediate cavity between the first and second cavities (3 and 4) of the method of Lee so that the fluid flow between the two cavities is controlled until suitable transfer between the channels is so desired.

- 14. This use of Brown for Lee is further rendered obvious by Sundberg which teaches that the electrophoretic channels 78 might desire different fluids than in the channel that 76 that feeds the electrophoretic channel. Sundberg suggest that a feature 90 be placed between these crossing channels such that fluid can be placed in one channel 78 without that solution bleeding into the crossing channel. See Sundberg col. 9, Il. 26-50 and compare fig. 7 of Sundberg to fig. 2 of Lee. Because Sundberg has expressed the desire for structure that permits at least temporary isolation of one channel from a crossing channel in structure analogous to Lee, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the method of Lee so that fluid access to each of the channels can be separately controlled.
- 15. This use of Brown for Lee is further rendered obvious by the teaching of Hochstrasser which teaches in an analogous two-dimensional electrophoresis experiment that it is desired to keep the first dimension experiment isolated from the second dimensional experiment by an electrically insulating layer that can be solid, liquid, or gas (col. 2, II. 22-39). Because Hochstrasser has expressed the desire for structure that permits electrical isolation of a first dimensional electrophoresis experiment from the chamber for performing the second dimensional experiment, it would have been further obvious the utilize the intermediate cavity of

Art Unit: 1795

Brown between the first and second cavities (i.e. microchannels) of the method of Lee so that the second dimensional electrophoresis channels are isolated from the first dimensional electrophoresis channels during the performance of the first dimensional electrophoresis experiment.

- 16. With respect to claims 2 or 3, see abstract or par. 0040 of Lee.
- 17. With respect to claim 4, Brown already teaches that the separation substance is air and the connection medium is whatever the fluid being placed in the connected microchannels (col. 8, ll. 22-32). The fluid being placed in the channels of Lee would obviously include electroconductive fluid because electrophoresis would require charge carrying fluid.
- 18. With respect to claim 5, Hochstrasser teaches that the electrical isolation can be provided by materials other than air such as fluids immiscible with the materials utilized for either of the first or second dimensional experiments (col. 4, II, 22-33).
- 19. With respect to claim 6, as discussed in the previous 6/1/2009 office action, Lee discloses all the limitations of the first cavity 3, second cavity 4, but does not explicitly teach the presence of intermediate cavity that connects the first and second cavities, but does discuss that it would be desirable to control the filling of each of the cavities (i.e. microchannels) separately (e.g. par. 0043 and 0044). The previously discussed Brown teaches the use of intermediate cavities between two different cavities (i.e. capillary channels) for controlling the fluid flow from one cavity to the other. See the rejection above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an intermediate cavity between the first and second cavities (3 and 4) in the device of Lee so that the fluid flow between the two cavities is controlled until suitable transfer between the channels is so desired.

Application/Control Number: 10/533,015

Art Unit: 1795

20. This use of Brown for Lee is further rendered obvious by Sundberg which teaches that the electrophoretic channels 78 might desire different fluids than in the channel that 76 that feeds the electrophoretic channel. Sundberg suggest that a feature 90 be placed between these crossing channels such that fluid can be placed in one channel 78 without that solution bleeding into the crossing channel. See Sundberg col. 9, Il. 26-50 and compare fig. 7 of Sundberg to fig. 2 of Lee. Because Sundberg has expressed the desire for structure that permits at least temporary isolation of one channel from a crossing channel in structure analogous to Lee, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the device of Lee so that fluid access to each of the channels can be separately controlled.

Page 7

- 21. This use of Brown for Lee is further rendered obvious by the teaching of Hochstrasser which teaches in an analogous two-dimensional electrophoresis experiment that it is desired to keep the first dimension experiment isolated from the second dimensional experiment by an electrically insulating layer that can be solid, liquid, or gas (col. 2, Il. 22-39). Because Hochstrasser has expressed the desire for structure that permits electrical isolation of a first dimensional electrophoresis experiment from the chamber for the second dimensional experiment, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the device of Lee so that the second dimensional electrophoresis channels are isolated from the first dimensional electrophoresis channels during the performance of the first dimensional electrophoresis experiment.
- 22. With respect to the limitation beginning "where the separation medium is replaced..." this limitation doesn't further define the actual structure of the device, but merely define how

Application/Control Number: 10/533,015

Art Unit: 1795

applicant intends to utilize the structure. However, even if the examiner were to give these limitations further due consideration see the discussion of the teaching of Brown and claim 1 above.

Page 8

- 23. With respect to claim 7, see the discussion of claim 2 above.
- 24. With respect to claim 8 (those limitations not covered for claim 6 above), the first cavity of Lee contains a first electrophoretic medium and the second cavity contains a second electrophoretic medium (par. 0041). With respect to the limitation beginning "where the separation medium is replaced..." this limitation doesn't further define the actual structure of the device, but merely define how applicant intends to utilize the structure. However, even if the examiner were to give these limitations further due consideration see the discussion of the teaching of Brown and claim 1 above.
- 25. With respect to claim 9, how the connection medium is introduced doesn't not further define the actual apparatus, but merely describes how the apparatus is desired to function. This intended use need not be given further due consideration in determining patentability. However, even if the examiner were to give these further limitations further due consideration, Brown teaches that the connection medium automatically flows once the outlet of the capillary channel is vented (col. 10, II. 18-43). This is either strongly suggestive of the use of capillary action or would have rendered obvious the use of capillary action as capillary action is a convenient passive means for causing fluid to flow through capillaries.
- 26. With respect to claim 10, Lee discloses introducing one or more proteins into the first cavity 3 and performing electrophoresis in the first cavity (par. 0046) and conducting electrophoresis on the one or more proteins in the second cavity (par. 0047). Furthermore,

Art Unit: 1795

Brown teaches air can be utilized as a separation medium in an intermediate cavity when no fluid contact between two different channels is desired followed by the insertion of connecting fluid when contact is so desired (see discussion above). Because the electrophoresis experiments in cavities 3 and 4 of Lee are supposed to happen separately and preferably in electrical isolation (see Hochstrasser), it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize intermediate cavity of Brown filled with air during the first electrophoresis experiment to keep the sample in the first cavity from prematurely entering the second cavity. After the conclusion of the first dimensional experiment, it would have been obvious to one of ordinary skill in the art to allow contact between the first and second cavities of Lee by introducing connecting medium into the intermediate cavity because at this point contact between the two different cavities is necessary to allow the sample from the first dimensional experiment to enter the second cavity for the second dimensional experiment.

Response to Arguments

 Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

Art Unit: 1795

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/ Primary Examiner, Art Unit 1795

December 31, 2009